DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

'99 AUG 12 P3:35

August 11, 1999

Lynda Sutton, B. Sc.
Cato Research
200 Westpark Corporate Center
4364 South Alston Avenue
Durham, NC 27113-2280

Re: Docket No. 97P-0437/CP1

Dear Ms. Sutton:

This responds to your citizen petition, dated October 20, 1997, requesting that the Food and Drug Administration (FDA) determine that the antinauseant drug composed of pyroxidine hydrochloride and doxylamine succinate (Bendectin) was not withdrawn from the market for safety or effectiveness reasons.

The FDA has reviewed its records and has determined that Bendectin was not withdrawn from sale for reasons of safety or effectiveness. This determination allows the FDA to include the drug product in the "Discontinued Drug Product List" of *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice of the FDA's determination. If you require any further information, please do not hesitate to call me at 301-594-2041.

Sincerely yours,

Andrea Masciale

Andrea Masciale
Regulatory Policy Staff
Center for Drug Evaluation and Research

Enclosure

97P-0437

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